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TITLE:

Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?

PRINCIPAL INVESTIGATOR:

Edna B. Foa

CONTRACTING ORGANIZATION:
University of Pennsylvania,
Philadelphia, PA 19104

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14. ABSTRACT
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15. SUBJECT TERMS- none provided

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INTRODUCTION

Prolonged exposure (PE) therapy for PTSD has many characteristics that render it an excellent candidate for dissemination: it is effective with a wide range of PTSD sufferers, it is relatively easy to learn and deliver, and it is preferred by patients over some other treatments. Research indicates that case consultation after participation in a workshop plays an important role in training mental health professionals to successfully implementing EBTs. However, consultation requires a greater investment of resources than a one-time workshop. Thus, it is critical to determine whether consultation increases the success of disseminating and implementing PE services in routine clinical care. This study will examine how we can successfully disseminate and implement EBTs for PTSD in the Army by comparing two PE training models: Standard PE training (workshop only) and Extended PE training (workshop plus consultation). Approximately 35 mental health therapists in each of three medium- to large-sized domestic Army installations will be randomly assigned to either implement Standard PE training or Extended PE training. We hypothesize that compared to Standard training, the Extended PE training will lead to: 1) Greater frequency and higher quality of PE delivery; and 2 Superior patient response to treatment 3) Higher provider self-efficacy and positive attitudes towards PE.

BODY

Between April 01 and July 01, 2013, Drs. Foa, McLean, Peterson, and Hoover visited all three study sites (Ft. Carson, Ft. Campbell, and Ft. Bliss) to meet with local leadership and identify a site PI. Dr. Brenda Hansen at Ft. Bliss agreed to serve as the site PI, MAJ Joseph Wise at Ft. Campbell agreed to serve as the site PI, and MAJ Weber at Ft. Carson agreed to serve as the site PI. Letters of commitment from all three study sites were secured. On February 26, 2013, Drs. Foa, McLean, Peterson, and Hoover met with COL Castro, LTC McGurk, and Drs. Irvin and Hoge in Ft. Detrick to discuss study design and methods. It was agreed that the study design would be altered by randomizing participants within study sites and delaying the local supervisor training until data collection was complete in order to increase internal validity. Drs. Foa and McLean revised the proposal, SOW, and budget to accommodate design changes made during the February 26 meeting.

To obtain IRB approval for the study, the protocol was first sent to the IRB of the coordinating site, the University of Pennsylvania. Drs. Foa and McLean, in coordination with Drs. Peterson

and Young--McCaughan, developed the study protocol (including all assessments) and the two consent forms (therapist-participant consent and patient-participant consent). The study protocol and consent documents were submitted to the University of Pennsylvania IRB in July 2013. The University of Pennsylvania IRB provided comments and requests for revisions to the study consents and protocol. Drs. Foa, Mclean, and Zandberg consulted with key study personnel and revised these documents to adequately address IRB concerns. A resubmission was made to the Penn IRB on September 13, 2013 and the University of Pennsylvania IRB granted approval on September 20, 2013. Next, the study protocol and consents for Ft. Carson will be submitted to the MAMC IRB.

The Geneva Foundation began advertising for the study staff positions at all three sites in April 2013. Initial recruitment efforts focused on the project coordinator position. Drs. Foa and McLean interviewed a number of candidates for each of the project coordinator positions. Ms. Jennifer Deluzio was offered the position of project coordinator at the Ft. Campbell site and she accepted the position with a start date of July 15, 2013. Ms. Allison Hancock was offered the position of project coordinator at the Ft. Carson site and she accepted the position with a start date of August 1, 2013. In September 2013, Dr. Mrudula Raparla was offered the position of project coordinator at Ft. Bliss and she accepted the position with an upcoming start date of October 1, 2013.At the University of Pennsylvania, a post-doctoral fellow, Dr. Laurie Zandberg, was hired and trained by Drs Foa and Mclean to help with coordination of the study. Dr. Zandberg's start date will be October 1, 2013. A research assistant (RA) at the University of Pennsylvania, Allison Chernov, will be trained to assist with the study.

Once the project coordinators were hired at each site, recruitment efforts focused on hiring the site RAs and the behavioral outcomes assessors (BOAs). In September 2013, Sally Curtis and Kristen Butcher were offered the RA positions at Ft. Carson and Ft. Campbell respectively and their start date will be October 7.All newly hired staff are completing hospital in processing, CITI, and IRB trainings.

From April 01 onward, one-hour weekly telephone conference calls have been conducted with Drs Foa, McLean, Zandberg and Allison Chernov at Penn, Drs Peterson and Young-McCaughan at UTSHCA, Miranda Bethay at the Geneva Foundation, and the on-site project coordinators: Dr.

Mrudula Raparla at Ft. Bliss, Dr. Jennifer Deluzio at Ft. Campbell, and Dr. Allison Hancock at Ft. Carson. Conferences calls have focused on IRB issues and hiring.

In August 2013, Drs. Mintz and Aguilar, in collaboration with Drs. Foa and McLean, developed procedures for data collection and a plan for database development. In addition, development of the PE supervisor's application began in September 2013 in collaboration with Drs. Kenneth Ruggiero, Alyssa Rheingold, and April Borkman at The Medical University of South Carolina. Conference calls were conducted to determine application content, structure, and presentation.

Problem Areas

The decision made on February 26, 2013 to change the study design did necessitate revisions to the study materials. Study collaborators, including leadership at the study sites were informed about the rationale for the change and were supportive and maintained their commitment to participate in this important study.

KEY RESEARCH ACCOMPLISHMENTS

- IRB protocol approved at Coordinating Site University of Pennsylvania
- Hired key study staff including three research coordinators and two RAs.

REPORTABLE OUTCOMES

None to date. IRB approval has not been obtained.

CONCLUSION

Accessibility of effective PTSD treatment is an extremely relevant issue for the military and for our national public health in general. The proposed research will help identify the most effective PE training model while ensuring sustainability of implementation and maintenance of treatment quality and adherence. This study constitutes a key step towards the ultimate goal of increased access to evidence-based treatment among soldiers suffering from PTSD and related problems. The results will inform EBT dissemination efforts in the military as well as the public sector.

REFERENCES

None

APPENDICES

1. The University of Pennsylvania IRB approval letter
2. Letters of commitment from Ft. Bliss
3. Letters of commitment from Ft. Carson
4. Letters of commitment from Ft. Campbell

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

23-Aug-2013

Edna B Foa
foa@mail.med.upenn.edu
Blockley Hall
423 Guardian Dr
Philadelphia, PA 19104-6021
Attn: Carmen McLean
mcleanca@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR	: Edna B Foa
TITLE	: Implementation of Prolonged Exposure in the Army: Is consultation necessary for effective dissemination?
PROTOCOL #	: 818540
REVIEW BOARD	: IRB #8
SPONSORING AGENCY	: Department Of Defense

Dear Dr. Edna Foa:

The above referenced protocol underwent full-board review by the above Institutional Review Board on 19-Aug-2013. The Committee withheld approval for the study pending your response to the following issues raised.

STIPULATIONS:

General:
1. Please revisit the documents submitted and make consistent the enrollment numbers for each group and at each site among all of the documents submitted.

2. Please verify in the response submission if any aspects of the research procedures are being videotaped. If no videotaping is anticipated to occur, please remove this as a proposed research procedure from the submission materials. If videotaping is planned, please revisit the submission materials (most notably the informed consent form) and include the videotaping procedures and any potential risks of videotaping.

3. Please submit a modification when all of the other sites receive their local site approvals from their own IRB.

4. Please confirm with the response submission that Rebecca Yeh should not be listed as a study contact (e.g. does not need edit access to the HS-ERA application). If you would like Rebecca to serve as a study contact, please revise the personnel page to include her on the “Study Contact” portion of the “Personnel” page. *Note: If adding the personnel to the application, please check for current CITI training or supply the CITI certification if the information in the application is not correct.

5. Please revise either the HS-ERA application or the HIPAA authorization form (or HIPAA section of the consent form) to align the listing of what protected health information subjects will have collected during their participation in the study.

6. Please verify that social security number is required to be obtained for the purposes of this research (i.e. for compensation of subjects). If social security number is not required, please remove this from the HS-ERA application, HIPAA authorization form (or HIPAA section of the informed consent form) or both.

7. Please include the alternatives to participation in this research in the risks tab of the HS-ERA application and the informed consent form.

HS-ERA Application:
8. Please revise the “UPHS” services question in the “SOC” section of the HS-ERA application from “Yes” to “No.”

Informed Consent Forms:
9. The convened board agreed with the comments provided by the previous reviewer. Please incorporate the revisions requested with your response submission in both the provider and patient informed consent forms.

10. Line 46 of the provider informed consent form; please include a description of the therapists’ role in the recruitment progress.

11. Line 46 of the provider informed consent form; please clarify how the therapists will be notified of who is qualified for the study.

12. Line 46 of the provider informed consent form; please include an explanation of how the assessment process and reassure the therapists that they will not be doing these assessments and it will not affect their schedule.

The following documents were submitted for review:

- HS-ERA Protocol Application (Confirmation: bcdjfbgg) submitted 07/15/13
- Grant Application uploaded 05/23/13
- Study Flow Chart uploaded 05/20/13
- Cover Letter dated 07/18/13
- Informed Consent Form (William Beaumont Army Medical Center) for Patients uploaded 07/17/13
- Informed Consent Form (William Beaumont Army Medical Center) for Therapists uploaded 07/17/13
- Audit pretreatment uploaded 07/18/13
- Audit post treatment uploaded 07/18/13
- BDI (lasttwoweeksv1.10.2013) uploaded 07/18/13
- BSS Questionnaire uploaded 07/18/13
- Credibility Expectancy Questionnaire uploaded 07/18/13
- CSQ8 Questionnaire uploaded 07/18/13
- Demographic Form Patient uploaded 07/18/13
- PCL-S Questionnaire uploaded 07/18/13
- 6 Extended Only-post Consultation Measure of Attitudes uploaded 07/18/13
- 76 Month Post Implementation Measure of Attitudes uploaded 07/18/13
- PTSD Pretracking Form uploaded 07/18/13
- PSSI-5 Questionnaire uploaded 07/18/13
- 1 Demographic Form-Participant uploaded 07/18/13
- 2 Therapist Pre-training Background Survey uploaded 07/18/13
- 3 Pre-Workshop Measure of Attitudes uploaded 07/18/13
- 4 Therapist Post-workshop Feedback Survey uploaded 07/18/13
- 5 Post-Workshop Measure of Attitudes uploaded 07/18/13
- State-Trait Anger Expression Inventory (STAXI) S-Anger Subscale (version20_02-28-2012) uploaded 07/18/13

Note: The convened board determined this study is minimal risk and future annual reviews can be conducted via the expedited mechanism (category 9).

Please send one (1) copy of the revised consent form(s) and any additional information to this office where the materials will be reviewed for final approval. To expedite your approval:

- Highlight any revisions in the consent form(s) and protocol.
- Provide a clean copy of the consent form(s), which will be stamped with the IRB approval and expiration dates.
- Provide a cover letter detailing how the Board's stipulations and recommendations were met.

If your protocol was originally submitted via the online HS-ERA application system, please do not submit paper documents but complete and submit your reply and revisions via HS-ERA.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/regulatoryaffairs.

Thank you for your cooperation.

Sincerely,

David Heagerty

Digitally signed by David Heagerty
DN: cn=David Heagerty, o=IRB, ou=ORA, email=heagerty@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this document
Date: 2013.08.23 14:30:21 -04'00'

IRB Administrator

30 April, 2013

Edna B. Foa, Ph.D.
Professor and Director Center for the Treatment and Study of Anxiety
University of Pennsylvania, Department of Psychiatry
3535 Market Street, 6th Floor
Philadelphia, Pennsylvania 19104

SUBJECT: Letter of Support for Prolonged Exposure Therapy Training study

Dr. Foa,

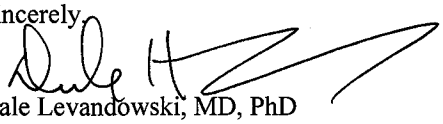
This Letter of Support is to document commitment in supporting your research study titled "Implementation of Prolonged Exposure in the Army: "Is consultation necessary for effective dissemination?" This study has been identified for funding through the Department of Defense Military Operational Medicine Joint Program Committee 5 Psychological Health/Traumatic Brain Injury Research Program to the University of Pennsylvania in collaboration with the STRONG STAR PTSD Research Consortium.

The wars in Iraq and Afghanistan have drastically increased the number of active duty soldiers identified as needing treatment for posttraumatic stress disorder (PTSD). There is strong scientific evidence and MEDCOM guidance for the use of Prolonged Exposure (PE) therapy in treating PTSD. Unfortunately, the use of PE is limited throughout the U.S. Army. One primary reason for the lack of implementation of PE is related to training and supervision. The proposed study is designed to examine whether Extended Training in PE will impact therapist behavior and treatment outcomes more than Standard PE Training.

I understand that participation in this study will involve the assessment and training of 40-45 mental health therapists at WBAMC. I understand that participants will be randomly assigned to receive Standard PE Training or the Extended PE Training. All therapists will receive an intensive 4-day workshop on the administration of PE to be conducted by Dr. Foa and colleagues, along with the distribution of training materials, and treatment manuals. Therapists in the Standard PE condition will be strongly encouraged to begin applying PE with the cases that they've identified as having PTSD symptoms, but no ongoing case consultation will be provided. In addition to the 4-day workshop, therapists in the Extended PE condition will receive close consultation on two PE training cases. This consultation will include weekly individual telephone consultation with an assigned PE expert. I understand that five research staff members will be provided to work at WBAMC to assist in the study including a doctoral-level project coordinator, a licensed clinical psychologist or clinical social worker, two master's level assessment evaluators, and a research assistant. In the final year of the study, a subset of trained PE therapists will also be selected to become local PE supervisors, so that supervision of PE therapists will continue in-house without the need for ongoing outside supervision instruction after the study ends. The therapists who are invited to become local supervisors will participate in a 5-day supervisor workshop in which they will be trained to provide peer PE consultation to other trained therapists on post.

I am very hopeful that we can establish a close collaboration between WBAMC, the University of Pennsylvania, and the STRONG STAR Consortium. We look forward to the opportunity of working with you on this project to improve the health and welfare of our Soldiers.

Sincerely,



Dale Levandowski, MD, PhD
COL, MC
Chief, Department of Behavioral Health (DBH)
William Beaumont Army Medical Center (WBAMC)
Ft Bliss, TX
915-742-2865

DEPARTMENT OF THE ARMY
Fort Carson Medical Department Activity
1650 Cochrane Circle
Fort Carson, Colorado 80913-4604

May 23, 2013

Edna B. Foa, Ph.D.
Professor and Director Center for the Treatment and Study of Anxiety
University of Pennsylvania, Department of Psychiatry
3535 Market Street, 6th Floor
Philadelphia, Pennsylvania 19104

SUBJECT: Letter of Support for Prolonged Exposure Therapy Training Study

Dear Dr. Foa,

This Letter of Support is to document our commitment in supporting your research study titled "Implementation of Prolonged Exposure in the Army: "Is consultation necessary for effective dissemination?" This study has been identified for funding through the Department of Defense Military Operational Medicine Joint Program Committee-5 Psychological Health/Traumatic Brain Injury Research Program to the University of Pennsylvania in collaboration with the STRONG STAR PTSD Research Consortium.

The proposed study is designed to examine whether Extended Training in PE will impact therapist behavior and treatment outcomes more than Standard PE Training.

I understand that participation in this study will involve the assessment and training of 40-45 mental health therapists at Ft Carson, CO. I understand that participants will be randomly assigned to receive Standard PE Training or the Extended PE Training. All therapists will receive an intensive 4-day workshop on the administration of PE to be conducted by Dr. Foa and colleagues, along with the distribution of training materials, and treatment manuals. Therapists in the Standard PE condition will be strongly encouraged to begin applying PE with the cases that they've identified as having PTSD symptoms, but no ongoing case consultation will be provided. In addition to the 4-day workshop, therapists in the Extended PE condition will receive close consultation on two PE training cases. This consultation will include weekly individual telephone consultation with an assigned PE expert. I understand that five research staff members will be provided to work at Ft Carson, CO, to assist in the study including a doctoral-level project coordinator, a licensed clinical psychologist or clinical social worker, two master's level assessment evaluators, and a research assistant. In the final year of the study, a subset of trained PE therapists will also be selected to become local PE supervisors, so that supervision of PE therapists will continue in-house without the need for ongoing outside supervision after the study ends. The therapists who are invited to become local supervisors will participate in a 5-day supervisor workshop in which they will be trained to provide peer PE consultation to other trained therapists on post.

I am very hopeful that we can establish a close collaboration between USA MEDDAC, Ft Carson, CO, the University of Pennsylvania, and the STRONG STAR Consortium. We look forward to the opportunity of working with you on this project to improve the health and welfare of our Soldiers.

Sincerely,

John M. McGrath
Colonel, U.S. Army
Commanding

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL DEPARTMENT ACTIVITY
FORT CAMPBELL, KENTUCKY 42223-5349

REPLY TO
ATTENTION OF:

JULY 30, 2013

Office of the Commander

Edna B. Foa, Ph.D.
Professor and Director Center for the Treatment and Study of Anxiety
University of Pennsylvania, Department of Psychiatry
3535 Market Street, 6th Floor
Philadelphia, Pennsylvania 19104

Dear Dr. Foa:

This Letter of Support is to document BACH's commitment in supporting the research study titled "Implementation of Prolonged Exposure in the Army: "Is consultation necessary for effective dissemination?" subject to the research project receiving the required approval. This study has been identified for funding through the Department of Defense Military Operational Medicine Joint Program Committee-5 Psychological Health/Traumatic Brain Injury Research Program to the University of Pennsylvania in collaboration with the STRONG STAR PTSD Research Consortium.

The wars in Iraq and Afghanistan have drastically increased the number of active duty soldiers identified as needing treatment for posttraumatic stress disorder (PTSD). There is strong scientific evidence and MEDCOM guidance for the use of Prolonged Exposure (PE) therapy in treating PTSD. Unfortunately, the use of PE is limited throughout the U.S. Army. One primary reason for the lack of implementation of PE is related to training and supervision. The proposed study is designed to examine whether Extended Training in PE will impact therapist behavior and treatment outcomes more than Standard PE Training.

I understand that participation in this study will involve the assessment and training of 25 mental health therapists at Ft Campbell, KY. I understand that participants will be randomly assigned to receive Standard PE Training or the Extended PE Training. All 25 therapists will receive an intensive 4-day workshop on the administration of PE to be conducted by Dr. Foa and colleagues, along with the distribution of training materials, and treatment manuals. Therapists in the Standard PE condition will be strongly encouraged to begin applying PE with the cases that they've identified as having PTSD symptoms, but no ongoing case consultation will be provided. In addition to the 4-day workshop, therapists in the Extended PE condition will receive close consultation on two PE training cases. This consultation will include weekly individual telephone consultation with an assigned PE expert. I understand that four research staff members will be provided to work at Ft Campbell, KY to assist in the study including a doctoral-level project coordinator, a licensed clinical psychologist or clinical social worker, a master's level assessment evaluator, and a research assistant. In the final year of the study, a subset of trained PE therapists will also be selected to become local PE supervisors, so that supervision of PE therapists will continue in-house without the need for ongoing outside supervision after the study ends. The therapists who are invited to become local supervisors will

participate in a 5-day supervisor workshop in which they will be trained to provide peer PE consultation to other trained therapists on post.

BACH's Chief of the Department of Behavioral Health, has fully briefed me on the requirements of BACH with regards to space a personnel and provides that BACH can support the research project.

I am very hopeful that we can establish a close collaboration between Ft Campbell, KY, the University of Pennsylvania, and the STRONG STAR Consortium. We look forward to the opportunity of working with you on this project to improve the health and welfare of our Soldiers. Of course, typical IRB and consents remain in place.

Sincerely,

Paul R. Cordts
Colonel, U.S. Army
Commanding